Randomized controlled study of the prediction of diminutive/small colorectal polyp histology using didactic versus computer-based self-learning module in gastroenterology trainees

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A RANDOMIZED CONTROLLED STUDY OF THE PREDICTION OF DIMINUTIVE/SMALL COLORECTAL POLYP HISTOLOGY USING DIDACTIC VS. COMPUTER BASED SELF-LEARNING MODULE IN GASTROENTEROLOGY TRAINEES

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Abbreviations:

PIVI- Preservation and Incorporation of Valuable endoscopic Innovations

NPV- Negative Predictive Value

NBI- Narrow band imaging

NICE- NBI International Colorectal Endoscopic classification

SIMPLE- Simplified Identification Method for Polyp Labelling during Endoscopy

SSA/L- Sessile serrated adenoma/lesion

HP- Hyperplastic polyp

iSCAN-OE- iSCAN Optical Enhancement

PPV- Positive predictive value

Abstract:

Background and aim:

The aim of this randomised trial was to evaluate the performance of self-training vs. didactic training, to increase the diagnostic accuracy of diminutive/small colonic polyp histological prediction by trainees.

Methods:

Sixteen trainees reviewed 78 videos (48 iSCAN-OE and 30 NBI) of diminutive/small polyps in a pre-training assessment. Trainees were randomised to receive computer-based self-learning (n=8) or didactic training (n=8) using identical teaching materials and videos. The same 78 videos, in a different randomised order, were assessed. The NICE (NBI International Colorectal Endoscopic) and SIMPLE (Simplified Identification Method for Polyp Labeling during Endoscopy) classification systems were used to classify diminutive/small polyps.

Results:

A higher proportion of high confidence predictions of polyps were made by the self-training vs. didactic group both using the SIMPLE classification 77.1% [95% CI 73.4-80.3] vs. 69.9%

[95% CI 66.1-73.5%] (p<0.005) and the NICE classification 77% [73.2%-80.4%] vs. 69.8% [95% CI 66-73.4%] (p=0.006). When using NICE, the sensitivity of the self-training group compared with the didactic group was 72% vs. 83% (p<0.0005), and the accuracy was 66.1% vs. 69.1%. The training improved the participants' confidence and SIMPLE was preferred over NICE.

Conclusion:

Self-learning for the prediction of diminutive/small polyp histology is a method of training that can achieve results similar to didactic training. The availability of adequate self-learning teaching modules could enable more widespread implementation of optical diagnosis in clinical practice.

Keywords: Colonic polyps, optical enhancement, virtual chromoendoscopy, narrow band imaging, polyp characterisation, training module

Introduction:

The majority (80%) of colonic polyps detected at colonoscopy are small/diminutive (<5mm), but despite the low risk of these lesions demonstrating advanced histology/cancer the current practice is to resect and send for histological analysis [1-3]. This carries risk in the form of unnecessary polypectomies of hyperplastic polyps (HP) and significant cost to health services, without a commensurate benefit [4, 5]. The ASGE-PIVI (American Society of Gastrointestinal Endoscopy- The Preservation and Incorporation of Valuable endoscopic Innovations) proposed "Resect and Discard" strategies which would allow significant cost

savings [6] with thresholds that need to be met before implementation in clinical practice [7]. Using novel endoscopic platforms "Optical Diagnosis" experts have demonstrated the ability to meet these thresholds, which include a Negative Predictive Value (NPV) ≥90% and agreement with surveillance intervals of ≥90% when predicting histology with high confidence [8]. However these results have not been replicated amongst non-experts [9].

In order to assist non-experts in reaching the PIVI thresholds criteria, endoscopic scoring systems have been developed, such as the NBI (Narrow Band Imaging) International Colorectal Endoscopic classification (NICE) [3] and SIMPLE (Simplified Identification Method for Polyp Labelling during Endoscopy) [10]. Integral to the implementation of these scoring systems is training with the optimum method unclear [11]. One study found a self-administered computerised teaching programme enabled community gastroenterologists to reach a NPV at predicting histology of ≥90% [12]. Attempts at training include the use of still images, videos, face-to-face didactic training and self-directed computer based learning [13, 14].

Khan et al. compared performance at predicting diminutive polyp histology amongst gastroenterology trainees using didactic training or computer-based self-learning [15]. There was no overall difference in prediction accuracy between the two groups. This gives promise to computer-based self-learning as a means to deliver training on a large scale. This study was limited by the fact that one endoscopic platform (NBI) and polyp classification system was used (NBI-based) as well as a modest number of videos assessed. The NICE classification has been extensively validated; however, it is limited by the lack of criteria for sessile serrated adenomas/lesions (SSA/L) [3]. The SIMPLE classification, which includes features of

SSA/L, was initially developed using the new iSCAN-OE (Optical Enhancement, Pentax-Japan) and subsequently was validated by using multiple endoscopic platforms [10].

In this randomised study, we aim to compare the performances of gastroenterology trainees at predicting histology of small/diminutive colonic polyps, following either face-to-face didactic training with an expert or computer-based self-learning, using different endoscopic platforms and polyp endoscopic classification scoring systems.

Methods:

Study design:

Participants were randomised in a non-inferiority randomized controlled study comparing didactic vs. self-learning on diagnostic performances of gastroenterology trainees at predicting histology of diminutive/small polyps. The study was approved by the research ethics committee at the University of Birmingham, UK (ERN_17-1370A). The trial was not registered at ClinicalTrials.gov as it was an educational study.

Participants:

We invited participants from 6 centres in the Midlands, UK to take part in the study that met the eligibility criteria: doctors in training without any endoscopic experience, gastroenterology trainees who have not yet completed training and ability to consent. The training was completed at the University of Birmingham Medical School, UK.

Video collection:

Seventy-eight high quality videos (48 iSCAN-OE/30 NBI) of small/diminutive colonic polyps were selected from an existing video library, which were used in an earlier study whereby expert endoscopists achieved a NPV of 91% (78-98) using the SIMPLE classification following training[(10)]. The iSCAN videos showed polyps in high definition white light (HD-WL) and iSCAN-OE in different modes. The NBI videos showed polyps in HD-WL and NBI, both without magnification. Each video was 30-90 seconds in duration and allowed individuals to pause the video to assess polyps in detail replicating real-life practice. Two endoscopic platforms were chosen since trainees often encounter more than one endoscopic platform during their training and during their career. Therefore training needs to reflect this and be validated in more than one platform.

Pre-training assessment phase:

Prior to the training participants viewed the 78 videos of small/diminutive colonic polyps and recorded the following observations on an Excel document (Microsoft Inc., Redmond, Washington, USA): Quality of Video (High/Low), NICE classification (Type 1, Type 2 or Type 3), Confidence level (High/Low), SIMPLE classification (Type 1, Type 2a or Type 2b) and Confidence level (High/Low). (Video 1 and 2)

Intervention:

Training:

Didactic training:

Training was conducted in a classroom for those participants randomised to receive didactic training, with training provided via a PowerPoint (Microsoft Inc., Redmond, Washington, USA) presentation by an expert endoscopist. An endoscopist with extensive experience in optical characterisation in NBI and iSCAN platforms (MI) reviewed all teaching material. Included in the presentation was an overview of "Resect and Discard", endoscopic platforms (NBI and iSCAN), NICE classification, SIMPLE classification and example still images (n=43) and videos (n=8) of both classifications in use (Figures 1-2). A large number of still images were used to ensure participants had the best opportunity to observe and learn Kudo Pit Patterns and other polyp features without movement artefact before observing videos, which are more challenging to interpret. Participants within this group had opportunity to ask questions and receive feedback in an interactive fashion. The trainer then discussed a number of videos demonstrating the use of NICE and SIMPLE in both NBI and i-SCAN platforms with the histology being revealed to the participants. All lesions demonstrated in the videos and images had been resected and sent for histological confirmation. The training took approximately 1 hour to complete.

Computer-based self-learning:

Participants randomised to the computer-based self-learning group were given the same PowerPoint presentation (Microsoft Inc., Redmond, Washington, USA) as the didactic group

and completed the training in a separate room. Participants completed training without feedback interaction. They reviewed the same number of videos as the didactic group, which had guidance on the polyp features using the NICE and SIMPLE classifications.

Post-training assessment:

Following training, participants completed a post-training assessment on the same day. These were the same 78 videos as the pre-training assessment in a different random order to reduce recall bias. Participants completed the same observations as per the pre-training assessment.

Randomization:

Each participant was allocated a computer-generated random number on Microsoft Excel (Microsoft Inc., Redmond, Washington, USA) following which computerised randomisation to either computer-based self-learning or didactic training took place at a 1:1 ratio. Due to the nature of the study blinding of participants was not possible. Randomisation, participant enrolment and intervention assignment was completed by SS.

Study outcomes:

The outcome measures included sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and accuracy of polyp histology predictions. In addition other outcome measures included proportions of high confidence predictions and inter-observer agreement.

Sample size:

Assuming a non-inferiority trial with one-sided distribution (face-to-face training vs. computer-based training) and power of 90% to detect a 5% difference in accuracy, the sample size required is 375 observations (one video=one observation per participant). As we used 78 videos, we would need a minimum of 5 participants in each arm. To minimise any potential errors we aimed to recruit at least 16 participants.

If calculating sample size independently for either modality, NBI and iSCAN-OE, a sample size of 750 would be needed. Sixteen trainees were recruited giving a total number of 1248 observations, therefore achieving necessary sample size to reach 90% power.

Statistical analysis:

All data was collected on Microsoft Excel (Microsoft Inc., Redmond, Washington, USA), and participants were allocated a study identification code to allow tracking of results from pre- to post-training. Predictions of polyp histology were compared with histological results as gold standard. Comparison between groups were made using Fisher's Exact Test. Inter-observer agreement was quantified using Fleiss' Kappa. This is an analogue to Cohen's Kappa for when more than two raters are used. Confidence intervals and p values were calculated using a bootstrap approach with 1000 iterations. Participant characteristics were analysed using a Wilcox-Rank sum test and Fisher's exact test. A p-value of <0.05 was considered statistically significant. Statistical analysis was performed using STATA 13.1 for Mac (Stata Corp. LP, College Station, Texas, USA).

Results:

Sixteen trainees (12 gastroenterology trainees and 4 endoscopically-naïve trainees) participated in the study with 8 trainees (6 gastroenterology trainees and 2 naïve trainees) randomised to receive computer-based self-learning and 8 trainees (6 gastroenterology trainees and 2 naïve trainees) to receive didactic training. Baseline characteristics for participants are shown in Table 1. There was no statistically significant difference in the prior endoscopic experience of each group. No participants were withdrawn from the study and all completed the pre- and post-training assessments (Figure 3).

Performances of the naïve and trainee endoscopists pre- and post-training when using NICE and SIMPLE classification are shown in Table 2. The performance in predicting histology in both groups (didactic and computer-based self-learning) are shown in table 3 and 4. Following training the proportion of predictions made with high confidence was higher in the computer-based self-learning group when using both the NICE 77% (73.2-80.4% 95% CI) and SIMPLE classifications 77.1% (73.4-80.3 95% CI) than the didactic group 69.8% (66-73.4% 95% CI; $p<0.05$) and 69.9% (66.1-73.5% 95% CI; $p <0.05$) respectively. When comparing performances, the didactic group demonstrated a higher sensitivity of 83.1% (78.7-86.9% 95% CI) over the computer group 72% (66.9-76.6% 95%CI) when using the NICE classification. There was no statistical difference between the two groups in other performance measures.

When comparing the inter-observer agreement (table 5), it was clear that training improves the agreement when using the SIMPLE classification, from 0.35 (0.29-0.42 95% CI) to a moderate agreement of 0.52 (0.45-0.61 95% CI; $p <0.0001$).

Following the training module participants gave feedback on the teaching and the polyp classifications (table 6). The training improved the participants' confidence at assessing small/diminutive polyps and of the classifications used, and SIMPLE was preferred over NICE.

Discussion:

Our study demonstrates that self-learning training can be effective for the prediction of diminutive/small polyp histology. This training method can achieve results similar to the more labour intensive and expensive didactic training method. To our knowledge, this paper is the first in the literature to compare two classification systems, NICE and SIMPLE and the impact of a training module on both. Secondly, we used two endoscopic platforms (NBI and iSCAN-OE), which again is a first in the literature and differs from the Khan *et al* paper [15]. This is the first study comparing didactic training with computer-based training using iSCAN-OE platform and the newly developed SIMPLE classification of small/diminutive colonic polyps. This is particularly important, as clinicians will have access to different endoscopic platforms (Olympus, Pentax and Fujifilm). Therefore when designing a training module, it needs to be effective for several platforms and restricting to one platform means results cannot be generalised.. Another strength of the present study was the number of observations made, both in the pre-training and post-training assessments. Sixteen participants assessed 78 videos giving a total of 1248 observations, allowing sufficient power to investigate for any difference between the two groups, and also independently for NBI and iSCAN-OE platforms, as the two platforms may have similarities as well as differences in the operating characteristics of training and inter-observer agreement. This is

significantly more than the 680 observations made by the Khan et al paper [15]. Further to this, participants completed a pre-training assessment before receiving either computer-based self-learning or didactic training, followed by a post-training assessment. This allowed us to fully assess the impact the training module in both modalities has on the performance of participants. We also used videos of polyps and allowed participants to pause the video, similar to holding or taking a picture during a real colonoscopy examination thereby allowing assessments from several angles, reproducing real-world performance.

Interactive still images (annotated with arrows and circles) gave trainees the best opportunity to observe and learn mucosal and vascular patterns and polyp characteristics using NICE and SIMPLE classifications systems without movement artefact. This was used to gain a baseline level of knowledge before testing on videos, which is more challenging with the polyp moving and more difficult to standardize. However, we did not solely use videos in the training as it takes time to observe videos and we wanted to ensure training could be delivered within 1 hour to ensure maximum effective learning and efficiency.

The most effective method in how to train non-experts in the prediction of small/diminutive polyp histology remains to be assessed. Didactic training with an expert endoscopist is an attractive method since it allows the opportunity to ask questions and receive feedback, with studies demonstrating it can be effective [16-18]. However it is resource intensive, time consuming and expensive, which means this method will unlikely be able to train significant numbers of non-experts. Computer-based learning is a common method of training and is relatively inexpensive, not resource intensive and can be delivered to a large number of participants in multiple countries. There is growing evidence demonstrating it can be an

effective method of training in optical diagnosis [12, 13, 19]. The drawbacks to this method are the lack of feedback possible and the inability to ask questions.

We demonstrated that the computer-based self-learning group predicted histology with higher confidence, using both NICE and SIMPLE classifications with the number of high confidence observations increasing following training in both classifications (SIMPLE and NICE). There may be an element of self-satisfaction associated with self-learning, whereas having direct feedback on polyp characteristics that participants may not have acknowledged may reduce confidence levels, as may be the case in the didactic group. There were elements of feedback in the self-training group in that histology was revealed with explanations using the NICE and SIMPLE classification. The fact that performances were similar in both groups highlights that the role of direct feedback face-to-face is less pivotal as was once anticipated. This will be incorporated into self-training as tested in this study.

In terms of diagnostic performance, the didactic group demonstrated a higher sensitivity at differentiating small/diminutive polyps when using the NICE classification. Otherwise, there was no statistical difference between the two groups. This further supports the findings from Khan et al [15], and shows promise that computer-based self-learning can have a role in training. Importantly, the NPV in both groups failed to reach the PIVI threshold, demonstrating that training modules, whilst having a role, should not be used in isolation and are an important component of teaching. The inter-observer agreement improved following training when using both NICE and SIMPLE classifications, with SIMPLE having a higher kappa agreement over NICE classification.

There are some limitations to this study. Firstly, the same videos were used in the pre- and post-training assessment in a random order to reduce recall bias. However, in using 78 videos the impact of this would be minimal as it allowed us to increase the number of observations made. In order to minimise this, different sets of videos matched for histology and endoscopic platform would need to be used which would need a large library of videos. These results cannot be generalised to Blue-light Laser Imaging (BLI) and other classifications systems such as BASIC (BLI Adenoma Serrated International Classification) [(20)]. We have not used the NBI Expert Team (JNET) classification [(21)] which has been demonstrated to characterize polyps using magnification with high accuracy [(22)]. However optical zoom magnifying endoscopes are not widely used in clinical practice in Western countries. Therefore we have not used magnifying images/videos in our training materials in order to replicate the endoscopic platforms that are likely to be encountered on a daily basis. The newly developed near focus with electronic zoom endoscope system (Exera III and Lucera Elite, Olympus) can now provide similar images and have been increasingly adopted in Western countries . This will enable implementation of the use of the JNET classification in the future and training modules will need adaptation.

In conclusion, we demonstrated a well-designed computer-based self-training module is as effective as didactic training. This gives promise to the widespread delivery of effective training to colonoscopists, improving the prospect of a “resect and discard” strategy. Computer-based self-learning is a training method that many trainees are familiar with its use in training. Its main advantages are that it is low cost and its ease of delivery. While individual feedback cannot be delivered as per didactic training, well-constructed explanations of lesions and the use of classification systems can allow for this. Further

studies should investigate if a combination of training modules in a stepwise approach might be the right future strategy into how to best achieve the PIVI thresholds, which may include training using live endoscopy.

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Figures and videos legends

Figure 1. Example slides from the Diminutive/Small colorectal polyp training module. Images show adenomatous polyps under High Definition, iSCAN-OE (left) and NBI (right) with polyp specific features highlighted.

Figure 2. Images show hyperplastic polyps under High Definition, iSCAN-OE (left) and NBI (right) with polyp specific features highlighted.

Figure 3. Participant flow diagram

Video 1: Representative video of adenoma using the different modes of iSCAN-OE (iSCAN 1 and iSCAN-OE)

Video 2: Representative video of Hyperplastic polyp using High definition white light and NBI mode

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Table 1.

Baseline characteristics of participants.

	Didactic training	Computer-based self-training	P-value
Gastroenterology years of experience (median)	3 (0-5)	3 (0-5)	0.705
Number of colonoscopies in lifetime (median)	145 (0-360)	105 (0-600)	0.958
NBI experience (%)	50% (4/8)	37.5% (3/8)	1
iSCAN experience (%)	12.5% (1/8)	12.5 (1/8)	1

Table 2. Pre-training vs. Post-training performance

SIMPLE Pre-Training				SIMPLE Post-Training		
	Naïve (%, 95% CI)	Trainee (%, 95% CI)	P-Value	Naïve (%, 95% CI)	Trainee (%, 95% CI)	P-Value
Sensitivity	72 (63-78)	74 (70-78)	0.479	76 (68-82)	82 (78-85)	0.093
Specificity	50 (42-58)	60 (55-65)	0.056	57 (49-66)	50 (45-54)	0.115
PPV	63 (56-70)	69 (65-73)	0.144	69 (61-75)	67 (63-70)	0.657
NPV	59 (49-68)	65 (60-70)	0.223	66 (56-74)	69 (63-74)	0.489
Accuracy	62 (56-67)	68 (64-71)	0.067	67 (62-73)	67 (64-70)	1
NICE Pre-Training				NICE Post-Training		
Sensitivity	63 (56-70)	71 (67-75)	0.057	74 (67-81)	79 (75-82)	0.248
Specificity	64 (55-72)	62 (57-66)	0.687	55 (46-63)	55 (51-60)	0.922
PPV	69 (61-76)	69 (65-73)	0.845	67 (60-74)	69 (65-72)	0.721
NPV	58 (50-66)	64 (59-68)	0.280	64 (54-72)	68 (62-73)	0.433
Accuracy	64 (58-69)	67 (64-70)	0.299	66 (60-71)	68 (65-71)	0.402

Table 3. Diagnostic performance at predicting small/diminutive polyp histology.

		Didactic training % (95% CI)	Computer-based self-training % (95% CI)	P value
SIMPLE	Sensitivity	83 (78-86)	78 (73-82)	0.148
	Specificity	52 (46-58)	51 (48-57)	0.735
	PPV	68 (63-72)	66 (61-71)	0.551
	NPV	71 (64-77)	65 (58-72)	0.249
	Accuracy	69 (65-73)	66 (62-69)	0.225
	High confidence predictions	70 (66-74)	77 (73-80)	0.005
NICE	Sensitivity	83 (79-87)	72 (67-77)	0.0005
	Specificity	52 (46-58)	59 (53-65)	0.106
	PPV	68 (63-73)	68 (63-73)	0.939
	NPV	71 (65-77)	63 (57-69)	0.059
	Accuracy	69 (65-73)	66 (62-69)	0.275
	High confidence predictions	70 (66-73)	77 (73-80)	0.006

Table 4. Performances using NICE and SIMPLE classification in the two groups

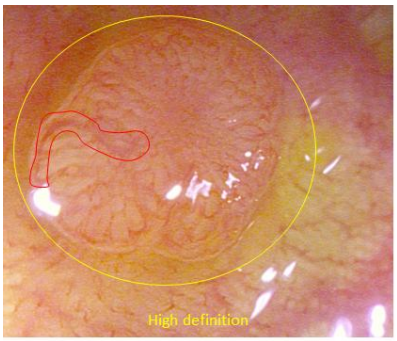
SIMPLE-Didactic Training			
	Pre-training % (95% CI)	Post-training	P-value
Sensitivity	75 (70-80)	83 (78-86)	0.018
Specificity	61 (55-67)	52 (46-58)	0.031
PPV	70 (65-75)	68 (63-73)	0.532
NPV	68 (60-72)	71 (64-77)	0.361
Accuracy	69 (65-73)	69 (65-73)	1
High confidence	46 (41-50)	70 (66-74)	<0.001
NICE-Didactic Training			
Sensitivity	76 (71-80)	83 (79-87)	0.018
Specificity	60 (54-66)	52 (46-58)	0.073
PPV	70 (65-75)	68 (63-73)	0.591
NPV	66 (60-72)	71 (65-73)	0.264
Accuracy	69 (65-72)	69 (65-73)	0.807
High confidence	55 (49-60)	70 (66-73)	<0.001
SIMPLE-Computer-based self-training			
Sensitivity	72 (66-76)	78 (73-82)	0.063
Specificity	54 (48-60)	51 (45-57)	0.498
PPV	65 (60-70)	66 (61-71)	0.880
NPV	61 (54-67)	65 (59-72)	0.334
Accuracy	64 (60-67)	66 (62-69)	0.439
High confidence	50 (46-54)	77 (73-80)	<0.001
NICE- Computer-based self-training			
Sensitivity	63 (58-68)	72 (67-77)	0.012
Specificity	65 (59-70)	59 (53-65)	0.164
PPV	69 (63-74)	68 (63-73)	1
NPV	59 (53-64)	63 (57-69)	0.343
Accuracy	64 (60-67)	66 (62-70)	0.373
High confidence	61 (57-65)	77 (73-80)	<0.001

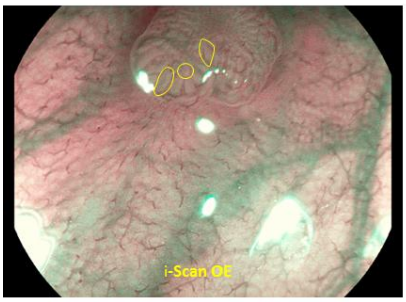
Table 5. Inter-observer agreement comparison

	Pre-training	95% CI	Post-training	95% CI	P-value
SIMPLE	0.349	0.286-0.417	0.523	0.447-0.612	<0.0001
NICE	0.295	0.231-0.354	0.346	0.298-0.464	0.168

Table 6. Participant's feedback

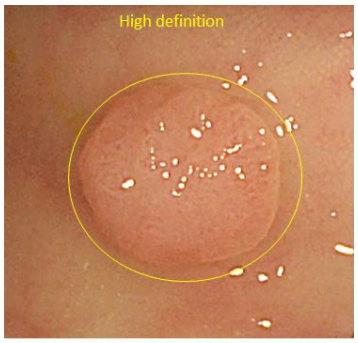
Q1. Did you find the training module useful?	Yes 15 (100%)	No 0 (0%)
Q2. Do you feel more confident assessing small/diminutive polyps?	Yes 14 (93.3%)	No 1 (6.67%)
Q3. How useful did you find the NICE classification? 0 not useful 10 Very useful	Median response 6.00 (95% CI 5.57-7.23)	
Q4. How useful did you find the SIMPLE classification? 0 not useful 10 Very useful	Median response 8.00 (95% CI 7.68-8.72) p=0.0005	
Q5. Which classification do you feel you will use in everyday practice?	NICE 1 (6.67%), SIMPLE 6 (40%), Both 8 (53.33%)	
Q6. How would you rate the quality of training? 0 not useful 10 Very useful	Mean response 9	

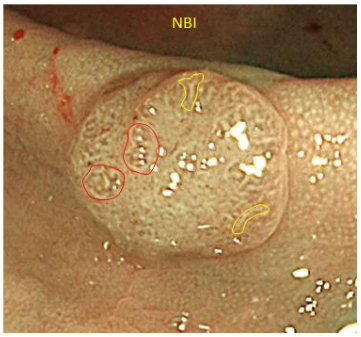


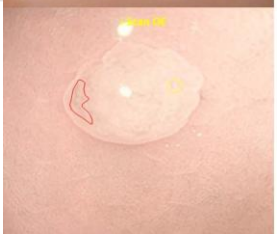


SIMPLE	NICE
Lesion border: Regular	Colour: Browner relative to background
Vessel pattern: Thick	Vessels: Brown vessels surrounding white structures
Surface pattern: Tubular/oval	Surface pattern: Tubular/oval white structures

This is an adenoma

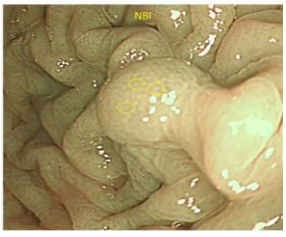






SIMPLE	NICE
Lesion border: Regular	Colour: Similar to background
Vessel pattern: None/Isolated lacy	Vessels: None
Surface pattern: Round pits	Surface pattern: Dark spots of uniform size

This is a hyperplastic polyp



CONSORT
TRANSPARENT REPORTING of TRIALS

CONSORT 2010 Flow Diagram